

§ 16.85

§ 16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§ 16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under § 16.1(a), the Commissioner shall consider the administrative record of the hearing specified in § 16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under § 16.1(b)—

(1) The administrative record of the hearing specified in § 16.80(a) constitutes the exclusive record for decision;

(2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and

(3) For purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

Subpart F—Reconsideration and Stay

§ 16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

Subpart G—Judicial Review

§ 16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regu-

21 CFR Ch. I (4–1–02 Edition)

latory action which is the subject of a hearing under this part

PART 17—CIVIL MONEY PENALTIES HEARINGS

Sec.

- 17.1 Scope.
- 17.3 Definitions.
- 17.5 Complaint.
- 17.7 Service of complaint.
- 17.9 Answer.
- 17.11 Default upon failure to file an answer.
- 17.13 Notice of hearing.
- 17.15 Parties to the hearing.
- 17.17 Summary decisions.
- 17.18 Interlocutory appeal from ruling of presiding officer.
- 17.19 Authority of the presiding officer.
- 17.20 Ex parte contacts.
- 17.21 Prehearing conferences.
- 17.23 Discovery.
- 17.25 Exchange of witness lists, witness statements, and exhibits.
- 17.27 Hearing subpoenas.
- 17.28 Protective order.
- 17.29 Fees.
- 17.30 Computation of time.
- 17.31 Form, filing, and service of papers.
- 17.32 Motions.
- 17.33 The hearing and burden of proof.
- 17.34 Determining the amount of penalties and assessments.
- 17.35 Sanctions.
- 17.37 Witnesses.
- 17.39 Evidence.
- 17.41 The administrative record.
- 17.43 Posthearing briefs.
- 17.45 Initial decision.
- 17.47 Appeals.
- 17.48 Harmless error.
- 17.51 Judicial review.
- 17.54 Deposit in the Treasury of the United States.

AUTHORITY: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

SOURCE: 60 FR 38626, July 27, 1995, unless otherwise noted.

§ 17.1 Scope.

This part sets forth practices and procedures for hearings concerning the administrative imposition of civil money penalties by FDA. Listed below are the statutory provisions that as of August 28, 1995, authorize civil money penalties that are governed by these procedures.

(a) Section 303 (b)(2) through (b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) authorizing civil money penalties for certain violations of the

act that relate to prescription drug marketing practices.

(b) Section 303(g) of the act authorizing civil money penalties for certain violations of the act that relate to medical devices.

(c) Section 307 of the act authorizing civil money penalties for certain actions in connection with an abbreviated new drug application or certain actions in connection with a person or individual debarred under section 306 of the act.

(d) Section 351(d)(2)(B) of the Public Health Service Act (the PHS Act) authorizing civil money penalties for violations of biologic recall orders.

(e) Section 354(h)(2) of the PHS Act, as amended by the Mammography Quality Standards Act of 1992, authorizing civil money penalties for failure to obtain a certificate, failure to comply with established standards, among other things.

(f) Section 2128 of the PHS Act authorizing civil money penalties for intentionally destroying, altering, falsifying, or concealing any record or report required to be prepared, maintained, or submitted by vaccine manufacturers pursuant to that section of the PHS Act.

§ 17.3 Definitions.

The following definitions are applicable in this part:

(a) For specific acts giving rise to civil money penalty actions brought under 21 U.S.C. 333(g)(1):

(1) *Significant departure*, for the purpose of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from requirements that is either a single major incident or a series of incidents that collectively are consequential.

(2) *Knowing departure*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(i), means a departure from a requirement taken: (a) With actual knowledge that the action is such a departure, or (b) in deliberate ignorance of a requirement, or (c) in reckless disregard of a requirement.

(3) *Minor violations*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(ii), means departures from requirements that do not rise to a level of a single major incident or a series of incidents that are collectively consequential.

(4) *Defective*, for the purposes of interpreting 21 U.S.C. 333(g)(1)(B)(iii), includes any defect in performance, manufacture, construction, components, materials, specifications, design, installation, maintenance, or service of a device, or any defect in mechanical, physical, or chemical properties of a device.

(b) *Person* or *respondent* includes an individual, partnership, corporation, association, scientific or academic establishment, government agency or organizational unit thereof, or other legal entity, or as may be defined in the act or regulation pertinent to the civil penalty action being brought.

(c) *Presiding officer* means an administrative law judge qualified under 5 U.S.C. 3105.

(d) Any term that is defined in the act has the same definition for civil money penalty actions that may be brought under that act.

(e) Any term that is defined in Title 21 of the Code of Federal Regulations has the same definition for civil money penalty actions that may arise from the application of the regulation(s).

(f) Any term that is defined in the PHS Act has the same definition for civil money penalty actions that may be brought under that act.

(g) *Departmental Appeals Board (DAB)* means the Departmental Appeals Board of the Department of Health and Human Services.

§ 17.5 Complaint.

(a) The Center with principal jurisdiction over the matter involved shall begin all administrative civil money penalty actions by serving on the respondent(s) a complaint signed by the Office of the Chief Counsel attorney for the Center and by filing a copy of the complaint with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

(b) The complaint shall state:

(1) The allegations of liability against the respondent, including the statutory basis for liability, the identification of violations that are the basis for the alleged liability, and the reasons that the respondent is responsible for the violations;